

(i) Patients who received transplants, including the date of transplant;

(ii) Patients awaiting a transplant who are medically able, have given consent, and are on an active transplant list, and projected transplants;

(iii) Home patients;

(iv) In-facility patients, staff-assisted, or self-dialysis;

(v) Individual patient diagnosis;

(vi) Diabetic patients;

(vii) Patients isolated because of contagious disease;

(viii) Age of patients;

(ix) Mortality rate, by age and diagnosis;

(x) Number of patient transfers, reasons for transfers, and any related information; and

(xi) Total number of hospital admissions for the facility's patients, reason for, and length of stay of each session.

(2) The facility also must—

(i) Submit documentation on costs of nursing personnel (registered nurses, licensed practical nurses, technicians, and aides) incurred during the most recently completed fiscal year cost report showing—

(A) Amount each employee was paid;

(B) Number of personnel;

(C) Amount of time spent in the dialysis unit; and

(D) Staff-to-patient ratio based on total hours, with an analysis of productive and nonproductive hours.

(ii) Submit documentation on supply costs incurred during the most recently completed fiscal or calendar year cost report showing—

(A) By modality, a complete list of supplies used routinely in a dialysis treatment;

(B) The make and model number of each dialyzer and its component cost; and

(C) That supplies are prudently purchased (for example, that bulk discounts are used when available).

(iii) Submit documentation on overhead costs incurred during the most recently completed fiscal or calendar year cost reporting year showing—

(A) The basis of the higher overhead costs;

(B) The impact on the specific cost components; and

(C) The effect on per treatment costs.

§413.186 Payment exception: Isolated essential facility.

(a) *Qualifications.* To qualify for an exception to the prospective payment rate based on being an isolated essential facility—

(1) The facility must be the only supplier of dialysis in its geographical area;

(2) The facility's patients must be unable to obtain dialysis services elsewhere without substantial additional hardship; and

(3) The facility's excess costs must be justifiable.

(b) *Criteria for determining qualifications.* In determining whether a facility qualifies for an exception based on its being an isolated essential facility, HCFA considers—

(1) Local, permanent residential population density;

(2) Typical local commuting distances from medical services;

(3) Volume of treatments; and

(4) The extent that other dialysis facilities are used by area residents (other than the applying facility's patients).

(c) *Documentation.* (1) *Isolated.* Generally, to be considered isolated, the facility must document that it is located outside an established Metropolitan Statistical Area and provides dialysis to a permanent patient population, as opposed to a transient patient population.

(2) *Essential.* To be considered essential, the facility must document—

(i) That a substantial number of its patients cannot obtain dialysis services elsewhere without additional hardship; and

(ii) The additional hardship the patients will incur in travel time and cost.

(3) *Cost per treatment.* The facility must—

(i) Document that its cost per treatment is reasonable; and

(ii) Explain how the facility's cost per treatment in excess of its composite rate relates to the isolated essential facility criteria specified in paragraph (b) of this section.

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(4) *Additional information.* The facility must also furnish the following information in a format that concisely explains the facility's cost and patient data to support its request:

(i) A list of current and requested payment rates for each modality.

(ii) An explanation of how the facility's costs in excess of its composite rate payment are attributable to its being an isolated essential facility.

(iii) An explanation of any unusual geographic conditions in the area surrounding the facility.

(iv) A copy of the latest filed cost report and a budget estimate for the next 12 months prepared on cost report forms.

(v) An explanation of unusual costs reported on the facility's actual or budgeted cost reports and any significant changes in budgeted costs and data compared to actual costs and data reported on the latest filed cost report.

(vi) The name, location of, and distance to the nearest renal dialysis facility.

(vii) A list of patients by modality showing commuting distance and time to the current and the next nearest renal dialysis facility.

(viii) The historical and projected patient-to-staff ratios and number of machines used for maintenance dialysis treatments.

(ix) A computation showing the facility's treatment capacity, arrived at by taking the total stations multiplied by the number of hours of operation for the year divided by the average length of a dialysis treatment.

(x) The geographic boundaries and population size of the facility's service area.

§413.188 Payment exception: Extraordinary circumstances.

(a) To qualify for an exception to the prospective payment rate based on extraordinary circumstances, the facility must substantiate that it incurs excess costs beyond its control due to a fire, earthquake, flood, or other natural disaster.

(b) HCFA will not grant an exception based on increased costs if a facility has chosen not to—

(1) Maintain adequate insurance protection against such losses (through

the purchase of insurance, the maintenance of a self-insurance program, or other equivalent alternative); or

(2) File a claim for losses covered by insurance or utilize its self-insurance program.

§413.190 Payment exception: Self-dialysis training costs.

(a) *Qualifications.* To qualify for an exception to the prospective payment rate based on self-dialysis training costs, the facility must establish that it incurs per treatment costs for furnishing self-dialysis and home dialysis training that exceed the facility's payment rate for such training sessions.

(b) *Justification.* To justify its exception request, a facility must—

(1) Separately identify those elements contributing to its costs in excess of the composite training rate; and

(2) Demonstrate that its per treatment costs are reasonable and allowable.

(c) *Criteria for determining proper cost reporting.* HCFA considers the facility's total costs, cost finding and apportionment, including its allocation of costs, to determine if costs are properly reported by treatment modality.

(d) *Limitation of exception requests.* Exception requests for a higher training rate are limited to those cost components relating to training such as technical staff, medical supplies, and the special costs of education (manuals and education materials). These requests may include overhead and other indirect costs to the extent that these costs are directly attributable to the additional training costs.

(e) *Documentation.* The facility must provide the following information to support its exception request:

(1) A copy of the facility's training program.

(2) Computation of the facility's cost per treatment for maintenance sessions and training sessions including an explanation of the cost difference between the two modalities.

(3) Class size and patients' training schedules.

(4) Number of training sessions required, by treatment modality, to train patients.